

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 845 Biomedical Research/Diseases
SPONSOR(S): Farkas and others
TIED BILLS: None. **IDEN./SIM. BILLS:** SB 2142 (i)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care		Rawlins	Collins
2) Workforce & Economic Development (Sub)			
3) Commerce			
4) Appropriations			
5)			

SUMMARY ANALYSIS

The bill establishes the Center for Universal Research to Eradicate Disease (CURED). The purpose of the center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use.

The center must hold an annual biomedical technology summit in Florida to which biomedical researchers, biomedical technology companies, business incubators, pharmaceutical manufacturers, and others around the nation and world are invited to share biomedical research findings. The center must encourage clinical trials in Florida on research that holds promise of curing a disease or condition. The center must facilitate partnerships between researchers, treating physicians, and community hospitals for the purpose of sharing new techniques and new research findings, as well as coordinating voluntary donations to ensure an adequate supply of adult stem cells, cord blood, and other tissues needed for biomedical research.

The center must also encourage the discovery and production in Florida of vaccines that prevent disease. The center must monitor the supply and demand for types of human tissue relating to research, including stem cell research, and other needs of researchers.

The center will be funded through private, state, and federal sources. The center will serve as a registry of all known biomedical grant opportunities and may assist any public or private biomedical research program in this state in preparing grant requests. The center must maintain a website with links to peer-reviewed biomedical research. The website must contain a list of all known biomedical research being conducted in Florida and must facilitate communication among researchers and other interested parties.

The center must submit an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than January 15 which contains recommendations for legislative change necessary to foster a positive climate for biomedical research in Florida. The duties of the center may be outsourced to a private entity or state university.

The bill requires that the long-term goals of the Florida Biomedical Research Program include the expansion of biomedical knowledge relating to cures, in addition to prevention, diagnosis and treatment, of diseases related to tobacco use. The bill requires that priority in grants awarded by the program be given to research aimed at preventing or finding cures for diseases.

The Department of Health estimates a fiscal impact of \$1,600 for travel expenses for department employees attending the statewide meeting.

The bill provides for an effective date of July 1, 2003.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h0845.hc.doc
DATE: April 8, 2003

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

- | | | | |
|--------------------------------------|---|--|------------------------------|
| 1. Reduce government? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 2. Lower taxes? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> | N/A <input type="checkbox"/> |
| 3. Expand individual freedom? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 4. Increase personal responsibility? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |
| 5. Empower families? | Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> |

For any principle that received a “no” above, please explain:

This bill expands the role of government by creating the Center for Universal Research to Eradicate Disease.

This bill does not lower taxes, rather uses additional tax dollar to fund the Center for Universal Research to Eradicate Disease.

B. EFFECT OF PROPOSED CHANGES:

Coordination of Biomedical Research

Biomedical research contributes ultimately to the health of a population, and biomedical discoveries and the resultant products or treatments contribute to the economy of the area where they are produced. For both health and economic reasons, governments have an interest in furthering the work of biomedical researchers and in helping researchers collaborate and share resources. A number of states have initiatives to coordinate cancer research. Some state governments as well as private foundations, and companies are addressing the need of researchers who are conducting stem cell research.

Stem Cell Research

Stem cells are cells that have the ability to divide for infinite periods in culture. They give rise to specialized cells. Research involving stem cells shows the possibility of treating diseases and conditions such as Alzheimer’s and Parkinson’s diseases, spinal cord injury, stroke, burns, heart disease, and arthritis. The possibility that an organ could be grown from stem cells has implications for tremendous changes in organ transplants.

A significant debate about stem cells involves the source of the cells. Human stem cells can be harvested from human embryos (embryonic stem cells) or from the tissue of an adult (adult stem cells). Human embryos are the source for pluripotent stem cells—cells that are capable of giving rise to most tissues of the human organism. The development of embryos for the sole purpose of harvesting the stem cells is considered immoral by many because the embryo is killed. In August 2001, President Bush announced that he would allow federal funding of research using the 60 existing stem cell lines. Thus federal funds will not pay for stem cell research that involves the destruction of human embryos.

In November 2001, President George W. Bush created The President’s council on Bioethics “to advise the president on issues that may emerge as a consequence of advances in biomedical science and technology” (Executive Order 13237). In particular, the council was authorized to study ethical issues connected with specific technological activities such as embryo and stem cell research. After studying the issue of human cloning, the majority, ten members of the council, voted to ban cloning for the production of children and to place a 4-year moratorium on cloning for biomedical research. The minority, seven members, voted to ban cloning for the production of children and to regulate the use of cloned embryos for research.

The Florida Biomedical Research Program and the Florida Biomedical Research Advisory Council
The 1999 Legislature established the Lawton Chiles Endowment Fund (ch. 99-167, L.O.F.), through which the state will use funds received as a result of its settlement with the tobacco industry to enhance or support expansions in children's health care programs, child welfare programs, community-based health and human service initiatives, and biomedical research.

Section 215.5602, F.S., establishes the Florida Biomedical Research Program funded from earnings of the endowment fund and provides that funds appropriated to the program are devoted to competitive grants and fellowships in research relating to diagnosis and treatment of tobacco-related illnesses including cancer, cardiovascular disease, stroke and pulmonary disease. The Biomedical Research Advisory Council in the Department of Health assists the Secretary in establishing criteria and guidelines for the competitive grant programs. Grants and fellowships are awarded on the basis of scientific merit, as determined by an open, objective peer-review process. The council is required to submit a progress report to the Governor, Secretary of the Department of Health, President of the Senate, and Speaker of the House of Representatives by February 1 of each year.

The Emerging Technology Commission

Under s. 1004.225, F.S., the "Florida Technology Development Act," the Emerging Technology Commission is a commission created within the Governor's Office for the purpose of guiding the establishment of centers of excellence within, and in collaboration with Florida's universities.

ITFlorida and The Florida Research Consortium

ITFlorida is a private umbrella organization comprised of both public and private technology leaders for high-tech in Florida. ITFlorida's stated mission is to make Florida a leader in high tech advancement, providing guidance to the state on technology issues and initiatives, guiding the Governor, the Legislature and Enterprise Florida on the strategic technology direction and initiatives of the state and working to ensure the successful integration of technology infrastructure statewide.

The Florida Research Consortium, an affiliated entity of ITFlorida, is governed by a board of high-tech industry leaders and university heads whose mission is to advise the Legislature and Office of the Governor on strategic policy initiatives for expanding and strengthening Florida's high-tech industries. The consortium aims to identify specific disciplines in science and technology where Florida has the greatest potential to achieve economic and academic successes –and to promote collaboration between academic and industrial researchers, scientists and engineers.

Enterprise Florida, Inc.

Enterprise Florida, Inc., created under part VII of ch. 288, F.S., is a partnership between Florida's business and government leaders and is the principal economic development organization for the State of Florida. The organization's mission is to increase economic opportunities for all Floridians by supporting the creation of quality jobs, a well-trained workforce and globally competitive businesses. It pursues its mission in cooperation with its statewide network of economic development partners.

BioFlorida

BioFlorida's mission is to promote biotechnology and related science in Florida by creating a favorable business and legislative environment; to provide the platform for business, academia and government to work jointly to support and encourage development of existing companies in the state and to attract new business and organizations to Florida.

The Florida Medical Foundation

The Florida Medical Foundation is the Florida Medical Association's philanthropic organization for medical education, research, community service, and physician support programs. The foundation emphasizes support for physicians at all stages of their professional careers. The foundation has a current project relating to doctor patient communications as a way of addressing the problem of low health literacy among patients.

Pharmaceutical Research and Manufacturers of America

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that improve the health and longevity of patients. The industry invested more than \$30 billion in 2001 in discovering and developing new medicines. PhRMA companies are involved in the search for new cures.

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The bill creates s. 215.5605, F.S., to establish the Center for Universal Research to Eradicate Disease (CURED). The purpose of the center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use. The goal of the center is to find cures for diseases such as cancer, heart disease, lung disease, diabetes, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease.

The center must hold an annual biomedical technology summit in Florida to which biomedical researchers, biomedical technology companies, business incubators, pharmaceutical manufacturers, and others around the nation and world are invited to share biomedical research findings in order to expedite the discovery of cures for diseases. Summit attendees will be required to cover the costs of their attendance or obtain sponsorship for such attendance.

The center must: encourage clinical trials in Florida on research that holds promise of curing a disease or condition; facilitate partnerships between researchers, treating physicians, and community hospitals for the purpose of sharing new techniques and new research findings, as well as coordinating voluntary donations to ensure an adequate supply of adult stem cells, cord blood, and other tissues needed for biomedical research; and encourage the discovery and production in Florida of vaccines that prevent disease.

The center must monitor the supply and demand for types of human tissue relating to research, including stem cell research, and other needs of researchers. If the center determines that there is a need for increased donation of human tissue, it must notify hospitals licensed under ch. 395, F.S., that have entered into partnership agreements with research institutes conducting stem cell research located in the same geographic region as the researchers demanding the stem cells or other tissues. The hospitals must then implement programs that encourage voluntary donations of cord blood or other needed tissues.

The center will be funded through private, state, and federal sources. The center will serve as a registry of all known biomedical grant opportunities and may assist any public or private biomedical research program in this state in preparing grant requests. The center must maintain a website with links to peer-reviewed biomedical research. The website must contain a list of all known biomedical research being conducted in Florida and must facilitate communication among researchers and other interested parties.

The center must submit an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than January 15 which contains recommendations for legislative change necessary to foster a positive climate for biomedical research in Florida. The duties of the center may be outsourced to a private entity or state university.

An advisory council, established within the center, must meet at least annually. The council will consist of the members of the board of directors of the Florida Research Consortium and at least one representative from:

- The Emerging Technology Commission;
- Enterprise Florida, Inc.;

- BioFlorida;
- The Florida Biomedical Research Advisory Council;
- The Florida Medical Foundation; and
- Pharmaceutical Research and Manufacturers of America.

Members of the council will serve without compensation and each organization represented must cover all expenses of its representative.

The bill amends s. 215.5602, F.S., which creates the Florida Biomedical Research Program, to require that the long-term goals of the program include the expansion of biomedical knowledge relating to cures, in addition to diagnosis and treatment, of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease. The bill requires that priority be given to research to prevent or cure disease.

The effective date of the bill is July 1, 2003.

C. SECTION DIRECTORY:

Section 1. Creates s. 215.5605, F.S., providing for the Center for Universal Research to Eradicate Disease; providing legislative intent and duties of the center; and creating an advisory council.

Section 2. Amends s. 215.5602, F.S., expanding the long-term goals and funding of the Florida Biomedical Research Program to include the cure of specified diseases.

Section 3. Provides for an effective date of July 1, 2003.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The Department of Health estimates a fiscal impact of \$1,600 for travel expenses for department employee attending the statewide meeting.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Private entities involved in biomedical research or furnishing supplies to biomedical researchers could benefit from the coordination that would be provided by the CURED.

D. FISCAL COMMENTS:

None

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenues.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Department of Health provided the following concerns:

Page	Line	Section 1 (215.5605)	Comment
2	39	(3)	Does not specify where the CURED is to be located in state government (DOH?)
3	68	(3)(f)	Under certain conditions hospitals “shall then implement programs that encourage voluntary donations” How will this be enforced? Is there penalty for not implementing “programs” as provided?
3	80	(3)(h)	The Center “may assist any public or private biomedical research program in this state in preparing grant requests.” There is potential conflict of interest between Advisory Council members (especially the BRAC member) and any grant award functions they may carry out for the Center or other state programs (i.e., Florida Biomedical Research Program).
4	94	(3)(k)	Does not specify who will be responsible for outsourcing; who is responsible for issuing an Invitation to Negotiate, for contract processing, for contract management
4	96	(4)	Does not provide council purpose or duties
4	98	(4)(a)	<ul style="list-style-type: none"> • Does not provide DOH representation • Does not specify who appoints the council members that are in addition to the board of directors of the Florida Research Consortium • Does not provide a term limit
4	107	(4)(b)	There is a fiscal impact for DOH support of one BRAC member serving on the Center’s advisory council. The impact depends on the level of involvement and travel requirements. Are the travel aspects limited by Ch. 112? The bill is silent on this. Does this duty include ADA accessibility expenses?

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES